

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 1-32 are in the case.

I. CLAIM OBJECTIONS

Claim 13 is objected to because of misspelling of the word "sleep". This has been corrected.

Claim 17 is objected to because it depends on any of claims 1-8. Claim 17 is now dependent on claim 1. Withdrawal of the claim objections is respectfully requested.

II. THE FORMAL REJECTIONS

Claims 9,19-20, and 25-28 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for treatment of grogginess, drowsiness, and lethargy, allegedly does not reasonably provide enablement for prevention of such symptoms. In response, and without conceding to the rejection, the term "prevention" has been deleted without prejudice.

Claims 1, 5,17-18, and 29-32 stand rejected as in "use" format. In response, the use claims are now presented in method format. Withdrawal of the formal rejections is respectfully requested.

III. THE 35 U.S.C. §101 REJECTION

Claims 1, 5,17-18, and 29-32 stand rejected under 35 U.S.C. §101 because the claims recite a use. The claims have been amended to obviate this rejection.

Withdrawal of the rejection is respectfully requested.

IV. THE OBVIOUSNESS REJECTIONS

Claims 1, 5, 9-13, 17-20, 26-28, and 30-31 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Monti *et al.* (Histamine H₁ Receptor Antagonists in the Treatment of Insomnia) (Monti) in view of Leung *et al.* (WO 00/1 8365) (Leung). Claims 25, 29, and 32 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Monti in view of Leung in further view of Hamilton *et al.* (A comparison of Triprolidine and cyclizine on histamine (H₁) antagonism, subjective effects and performance tests in man) (Hamilton). The rejections are respectfully traversed.

The claimed invention provides a method of aiding a person to wake refreshed after sleeping. The method comprises administering to the person a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient.

Monti describes the use of triprolidine as a treatment for daytime sleepiness and not as an aid to waking refreshed after sleep, as recited in the claimed method. The clinical studies in Monti relate to compounds other than triprolidine, and the "Conclusions" section states that there is an absence of a link between effects on the nighttime state and the waking state.

While Monti makes some general references to over-the-counter formulations as sleeping aids, none of those preparations includes triprolidine, as this was not an approved medication at that time. It is still not an approved sleeping aid. The only compound which is specifically taught as being a sleeping aid is diphenhydramine, which is significantly structurally different from triprolidine.

The general theme of Monti is that antihistamines should not be used as sleeping-aids. This is clearly evident from the first paragraph of the section entitled "Conclusions". Similarly, the last sentence of the second paragraph and the last paragraph of the Abstract both urge against the use of first generation anti-histamines as sleep-aids. It is also noted in section 2.2.1 entitled "Sleep Laboratory Evaluations" (page 90) that triprolidine was found to cause ". . . impaired performance during the day".

Based on the above, it is clear that one of ordinary skill would not have been motivated based on Monti to use triprolidine as a sleep-aid or as an aid to waking refreshed. Rather, the skilled artisan would look to benzodiazepine, cyclopyrrolone or one of the other compounds mentioned in Monti.

The deficiencies of Monti are not cured by the secondary art to Leung and Hamilton. Leung and Hamilton relate respectively to pharmaceutical formulations that may be consumable films, and that a preferred form of triprolidine is the hydrochloride salt. However, there is no suggestion in either Leung or Hamilton regarding the use of triprolidine as a sleep-aid.

It is clear from the above that Monti either alone or in combination with Leung and/or Hamilton does not give rise to a *prima facie* case of obviousness. Withdrawal of the obviousness rejections is respectfully requested.

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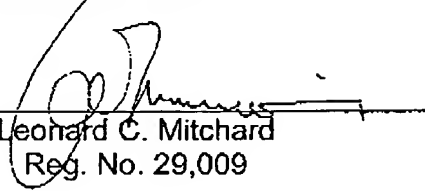
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Favorable action is awaited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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